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FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER PAVIGLIANITI, ANTHONY JOSEPH	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 02/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/725,277

Applicant(s)

TANG ET AL.

Examiner

Anthony J. Paviglianiti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 is/are ~~allowed~~ *allowable over the art of record. ATP*
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

Applicant's preliminary amendment of December 2, 2003 has been entered.

Accordingly, **Claims 8 – 25** are cancelled by that amendment, so that **Claims 1 – 7** are currently pending in the instant application.

Priority

This application is a division of Application No. 09/871,700, filed on June 4, 2001, and which became U.S. Patent 6,706,709. The application claims benefit of Provisional Application 60/209,162, filed June 2, 2000.

Information Disclosure Statement

The Information Disclosure Statement filed on December 2, 2003 is acknowledged and was considered by the examiner.

Election/Restrictions

The invention is the products of formula (I), as depicted in **Claim 1**.

The Markush groups set forth in the claims include both independent and distinct inventions, and patentably distinct compounds (or species) within each invention.

In accordance with the decisions in In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980) and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App & Int. 1984), restriction of a Markush group is proper where the compounds with the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference

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anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. §103 with respect to the other member(s).

Therefore, an election of a single compound is required, including an exact definition of each substitution on the base molecule of formula (I), where a single member at each substituent group, $R_1 - R_{10}$, is selected. For example, if the base molecule has a substituent group R_7 , where R_7 is recited to be “lower alkyl substituted with a heteroaliphatic ring or dialkylamino and lower alkoxy substituted with a heteroaliphatic ring or dialkylamino,” then applicant must select a single substituent representing R_7 , such as 2-morpholin-4-yl-ethoxy, and a specific value for R_2 , such as a bromine atom, and so on, such that there are specific values representing each subsequent variable position, so that a single compound is identified.

One suggestion for the election of a single compound would be to select one from the list of compounds in **Claim 7**, or to select one of the compounds described in Table 1 in the Specification at pp. 10 - 11.

In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim which fall into the same class and subclass as the elected compound, but may also include additional compounds which fall in related subclasses.

Examination will then proceed on the elected compound *and* the entire scope of the invention encompassing the elected compound as defined by common classification. A clear

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statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits.

Note that the restriction requirement will not be made final until such time as Applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making the compounds under investigation. This will be set forth by reference to specific class(es) and subclass(es) examined.

Should Applicant traverse on the ground that the compounds are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

All compounds falling outside of the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to non-elected subject matter and will be withdrawn from consideration under 35 U.S.C. §121 and 37 C.F.R. §1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. The provisions of 35 U.S.C. §121 apply with regard to double patenting covering divisional applications.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors are no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(i).

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If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can set forth a group of compounds which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP §608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

Rationale Establishing Patentable Distinctiveness Within The Invention

The invention is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP §806.04, MPEP §808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group); i.e., they are patentable over each other. Chemical structures which are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lahu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

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In addition, because of the number of classes and subclasses in the invention, a serious burden is imposed upon the examiner to perform a complete search of the defined areas. Therefore, for the reasons given above, the requirement for election set forth is proper, and not to require the election would impose a serious burden in the examination of this application.

During a telephone conversation with Steven Reid, Esq., on February 10, 2005, the above requirements were discussed, and applicant elected the compound 5-bromo-3-[5-(2-morpholin-4-yl-ethoxy)-1H-indol-2-ylmethylene]-1,3-dihydro-indol-2-one ("IN-008" in Table 1; also, Claim 7, Example 8) by telephone, without traverse. Applicant is advised that the reply to this requirement to be complete must include an election of the Invention to be examined even though the requirement be traversed. 37 C.F.R. §1.143.

Applicant is further advised that a reply to this requirement must include an identification of the specific compound that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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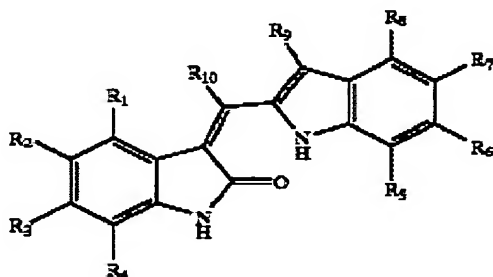
F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Double Patenting with U.S. Patent 6,506,763

Claims 1 – 6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 and 2 of U.S. Patent No. 6,506,763 B2, issued to Peng Cho Tang, et al. Although the conflicting claims are not identical, they are not patentably distinct from each other, because **Claim 1** of the instant application claims

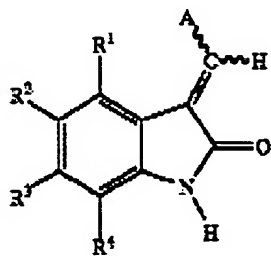


compounds of the structure

where the values for **R₁ –**

R₆ and **R₈ – R₁₀** may each be hydrogen but **R₇** (which distinguishes it from other prior art) must be a “substituted alkyl or substituted alkoxy” group, which duplicates (in part) the compounds encompassed by Claims 1 and 2 of U.S. Patent No. 6,506,763, which claimed compounds of the

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structure , where A is “a ring selected from the group consisting of naphthalene, tetrahydronaphthalene, pyridine, quinoline, **indole**, carbazole and uracil.”

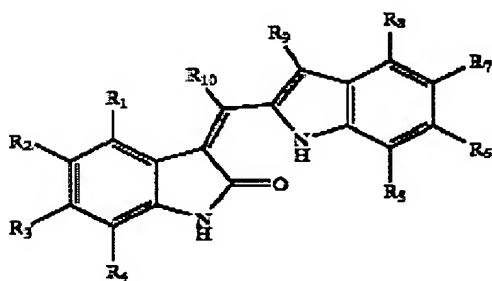
[emphasis added]. (col. 157, lines 43 and 60). Further, Claims 1 and 2 of U.S. Patent No.

6,506,763 claim ring A may be “substituted with one of more groups selected from ...

alkyl...alkenyl ... alkoxy heteroaryl, heteroalicyclic ...” Id. at lines 61 – 65.

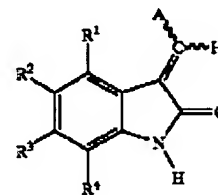
DETERMINING THE SCOPE AND CONTENTS OF THE CONFLICTING CLAIMS

The present invention claims compounds of the structure:



, where **R₁ – R₆** and **R₈ – R₁₀** may each be hydrogen

but **R₇** (which provides the novelty) must be a “substituted alkyl or substituted alkoxy” group.



U.S. Patent No. 6,506,763, which claimed compounds of the structure

where A is “a ring selected from the group consisting of naphthalene, tetrahydronaphthalene, pyridine, quinoline, **indole**, carbazole and uracil.” [emphasis added]. (col. 157, lines 43 and 60),

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where A is “substituted with one of more groups selected from ... alkyl...alkenyl ... alkoxy heteroaryl, heteroalicyclic ...”

The present invention and U.S. Patent No. 6,506,763 have a common inventor (Peng Cho Tang) and a common assignee, Sugen, Inc.

The compounds of the present invention and in U.S. Patent No. 6,506,763 are both disclosed as having the same biological activity, which is to “modulate the activity of protein kinases,” and both are claimed to be useful in treating diseases related to abnormal protein kinase activity, such as cancer. (See Specification at page 1, lines 15 – 17, page 2, lines 17 et seq.; compare U.S. Patent No. 6,506,763 at col. 1, lines 18 – 20, col. 2, lines 64 et seq.)

The claimed compounds in Claims 1 and 2 of U.S. Patent No. 6,506,763 do not have a subsequent dependent claim which specify a “preferred” value among the seven possible ring-types for A, or for its substituent group. In fact, the “method of use” claims in U.S. Patent No. 6,506,763 continue to list all seven ring types for A, including “indole,” as well as all of its possible substituents. (See Claims 20, 21, and 22 of U.S. Patent No. 6,506,763 at col. 159, line 65, col. 160, line 40, and col. 161, line 15). The Specification of U.S. Patent No. 6,506,763 also does not specify a “preferred” ring-type for A.

ASCERTAINING THE DIFFERENCES BETWEEN THE CONFLICTING CLAIMS

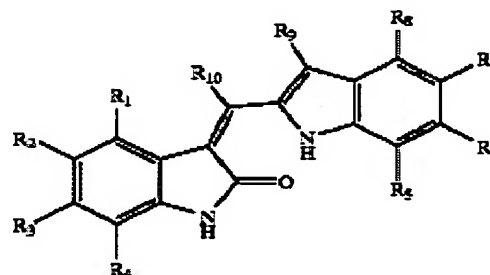
The present invention claims a more limited set of compounds than U.S. Patent No. 6,506,763; i.e., the present invention claims just one group (“indole”) where U.S. Patent No. 6,506,763 claimed seven possible groups (A = naphthalene, tetrahydronaphthalene, pyridine, quinoline, indole, carbazole and uracil).

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Also, the present invention limits the *attachment site* of the second indole ring to the 2-position (i.e., “indol-2-yl”), while U.S. Patent No. 6,506,763 does not specify the attachment site. In fact, the compounds listed as examples in U.S. Patent No. 6,506,763 where A = indole are generally attached via the “3”-position of the indole ring.

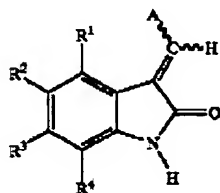
RESOLVING THE DIFFERENCES IN THE PERTINENT ART

The compounds of **Claims 1 – 6** of the instant application would have been obvious to one of skill in the art in light of conflicting Claims 1 and 2 of U.S. Patent No. 6,506,763. The



present invention claims compounds of the structure

where **R₁ – R₆** and **R₈ – R₁₀** may each be hydrogen but **R₇** (which distinguishes it from prior art) must be a “substituted alkyl or substituted alkoxy” group. U.S. Patent 6,506,763 claimed

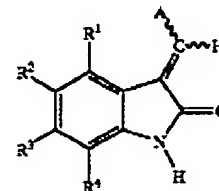


compounds of structure , where **A** is “a ring selected from the group

consisting of naphthalene, tetrahydronaphthalene, pyridine, quinoline, **indole**, carbazole and uracil,” [emphasis added] which is further substituted by alkyl or alkoxy groups, as noted in above. The present invention differs from U.S Patent 6,506,763 by limiting the ring-types for ring **A** to just one (“indole”), and by limiting the site of its attachment (via the methylene chain) to the 2-position of the indole ring. However, U.S. Patent 6,506,763 shows a preference for an

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indole ring at A (as compared with other heterocyclic rings) by including “indole” in its list of seven rings in Claims 1, 2, and 20 – 22. Therefore, at the time of this application, a person of



skill in the art would have been motivated to select compounds of structure

where A was represented by an “indole” ring, along with an alkyl or alkoxy substituent, attached via a methylene chain at the 2-position, which would anticipate the compounds in **Claims 1 – 6** of the present invention.

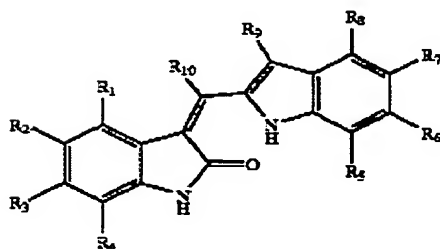
Double Patenting with Co-pending application 10/736,243

In addition, **Claims 1 – 6** of the present invention are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the co-pending application for patent 10/736,243, by Jingrong Cui, et al. A Notice of Allowance for the amended claims in Application 10/736,243 was sent on August 26, 2004, and the patent will be issued on March 1, 2005, as U.S. Patent 6,861,418.

The present invention and the Cui application share common inventors (Peng Cho Tang and Xiaoyuan Li) and a common assignee, Sugen, Inc.

DETERMINING THE SCOPE AND CONTENTS OF THE CONFLICTING CLAIMS

As noted above, the present invention claims compounds of structure:

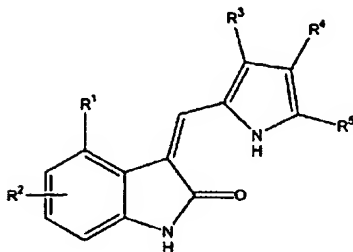


, where **R₁ – R₆** and **R₈ – R₁₀** may each be hydrogen but **R₇**

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(which distinguishes it from prior art) must be a “substituted alkyl or substituted alkoxy” group.

By comparison, the amended Claim 1 of the Cui application claims compounds of structure



, where “**R⁴** and **R⁵** may be linked together to form a 4-, 5-, 6- or

7-membered ring...which ring may contain 1 or 2 double bonds and may be further substituted

by one of more of $-(CH_2)_nNR^6R^7...$ ” Claim 2 of the Cui application claims the “compound of claim 1 wherein...**R⁴** and **R⁵** are linked together to form a ring.”

ASCERTAINING THE DIFFERENCES BETWEEN THE CONFLICTING CLAIMS

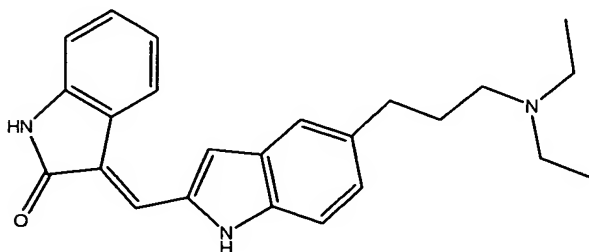
The present invention and the Cui application each have a 2-indolyl group attached to an 2-indolinone group via a methylene chain. The Cui application, however, does not specifically identify at *which* position the 2-indolyl group has substituents, while the present invention has variables **R₅ – R₈** at specified positions on the 2-indolyl group.

RESOLVING THE DIFFERENCES IN THE PERTINENT ART

The compounds of Claims 1 – 6 of the present invention would have been obvious to one of skill in the art in light of conflicting Claims 1 and 2 of the Cui application 10/736,243. Claim 1 of the Cui application was amended so that “**R⁴** and **R⁵** may be linked together to form a 4-, 5-, 6- or 7-membered ring...which ring may contain 1 or 2 double bonds and may be further substituted by one of more of $-(CH_2)_nNR^6R^7...$ ” Claim 2 of the Cui application depends on Claim 1 and indicates that the formation of a ring using **R⁴** and **R⁵** is a preferred embodiment of the invention. In addition, the first-listed substituent group on the 2-indolyl group in the Cui

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application is $-(CH_2)_nNR^6R^7$, which anticipates several of the preferred compounds in the present application, such as where $n = 3$ and NR^6R^7 = diethylamino to give the compound 3-[5-(3-diethylamino-propyl)-1H-indol-2-ylmethylene]-1,3-dihydro-indol-2-one



, which is Claim 7, example 1 in the present invention. A person of skill in the art would have been motivated to select a compound using preferred embodiments from the Cui application (i.e., R^4 and R^5 linked together to form a ring, and the first substituent listed, $-(CH_2)_nNR^6R^7$), and to place the substituent at *any* of the four positions on the indolyl ring. If the substituent were placed at the R_7 position, the compound would exactly anticipate several of the embodiments of **Claims 1 – 6** in the present invention.

Because the patent has not yet issued on the Cui application, this is a provisional obviousness-type double patenting rejection.

Claim Objections

Claims 2(b), 3(b) and 3(c), and 5(b) and 5(c) recite the word “halo” rather than “halogen,” which is inconsistent with **Claim 1(b)** [as values for variable R_2]. This may be corrected by amending each recitation of “halo” as “halogen” where it appears in the claims.

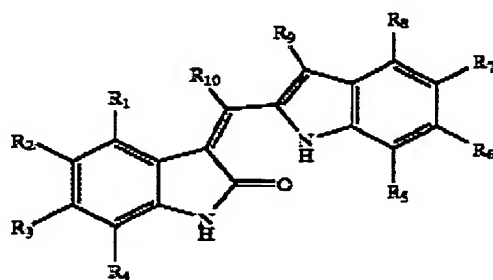
Analysis of Claim 7

For purposes of this examination, the search of the prior art encompassed the compound elected by applicant; i.e., 5-bromo-3-[5-(2-morpholin-4-yl-ethoxy)-1H-indol-2-ylmethylene]1,3-dihydro-indol-2-one (**Claim 7, Example 8**), as well as related compounds within the scope of the

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invention, including derivatives of 1H-indol-2-ylmethylene-1,3-dihydro-2-indolinone where **R₇** is either (1) alkyl- or alkoxy-*morpholinyl* groups (as in the elected invention), (2) alkyl- or alkoxy-*pyrrolidinyl* groups, or (3) alkyl- or alkoxy-*diethylamino* substituents, as classified in Class 544, subclass 144 and Class 548, subclass 455, respectively.

Claim 7 of the present invention describes forty-two (42) specific compounds of the

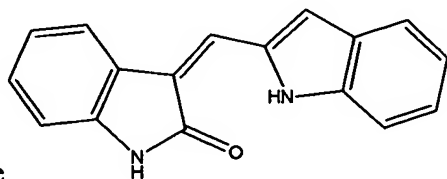


general formula

, each of which appears to be free of

the prior art.

The closest prior art was disclosed by Cinzia Lanzi of a compound with the



structure

, which discloses all of the limitations of Claim 1 in

the present invention except for the requisite substituent at the “5” position (i.e., **R₇**) on the

indolyl ring (“substituted alkyl [or] substituted alkoxy”). See C. Lanzi, “Inhibition of

Transforming Activity of the ret/ptc1 Oncoprotein by a 2-Indolinone Derivative,” Int. J. Cancer,

vol. 85, pages 384 – 390 (published online January 28, 2000), especially Compound 7 in Figure

1, on page 385 and page 384, 2nd col., lines 19 – 20. The Lanzi compound, like those

compounds in the present invention, had biological activity as an inhibitor of protein kinases. Id.

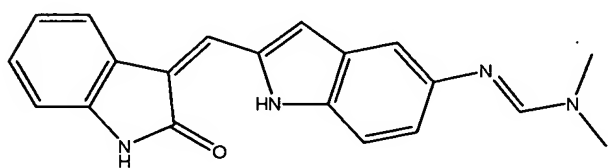
at p. 384, lines 15 – 20. However, the Lanzi reference did not teach any compounds with

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substituents at the “5” position of the indolyl ring, and therefore does not anticipate the compounds of the present invention.

U.S. Patent 4,642,309, by H. Michel, et al., likewise discloses a compound wherein 2-indolinone is linked to a 2-indolyl group via a methylene chain, but, like the Lanzi compound above, has no substituent at the “5” position of the 2-indolyl group and therefore does not anticipate the compounds of the present invention.

U.S. Patent 5,849,710, by Carlo Battistini, et al., discloses a compound of structure



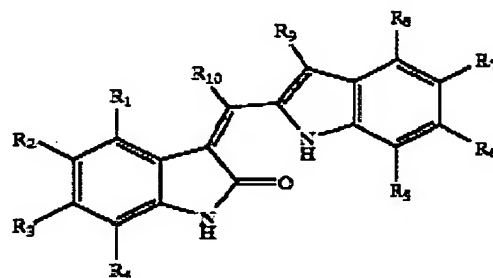
, which, unlike other art cited in this section, does have a substituent group at the “5” position of the indolyl ring (aminomethylene-dimethylamino). However, the instant application requires that R_7 be a “substituted alkyl [or] substituted alkoxy” group, which is not found in U.S. Patent 5,849,710. None of the compounds in **Claim 7**, and none of the examples in the instant Specification have an *amino* group which is double-bonded to a carbon atom at the “5” position of the indolyl ring; therefore, the Battistini reference does not anticipate the compounds of the present invention.

In addition, U.S. Patent 6,531,502 (first published as WO 00/08202 on Feb. 17, 2000) by Tang, et al., as well as a journal article by H. von Dobeneck in Chemische Berichte, vol. 102(4), pages 1347-56 (1969) (compound 19 on page 1351), both disclose a compound where 2-indolinone is linked to a 2-indolyl group via a methylene chain, but each has substituents at the “3” position of the indolyl group (dimethylpropyl and methyl groups, respectively) rather than at the requisite “5” position (“ R_7 ”). Neither one of these two references teaches that the substituent

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group may be moved or placed at the "5" position on the indolyl group, and therefore neither source anticipates the compounds of the present invention.

The forty-two compounds listed in **Claim 7** appear to be free of the art at this time. In



addition, those derivatives of the core structure:

where

R₇ is (1) alkyl- or alkoxy-*morpholinyl* groups, (2) alkyl- or alkoxy-*pyrrolidinyl* groups, or (3) alkyl- or alkoxy-*diethylamino* groups, also appear to be free of the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Anthony J. Paviglianiti** whose telephone number is (571) 272-3107. The examiner can normally be reached on Monday-Friday, 8:30 a.m. - 5:30 p.m.

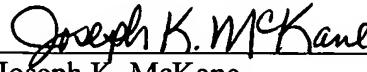
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, may be reached at (571) 272-0699. **The FAX phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Please note that this is a new central FAX number for all official correspondence.**

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